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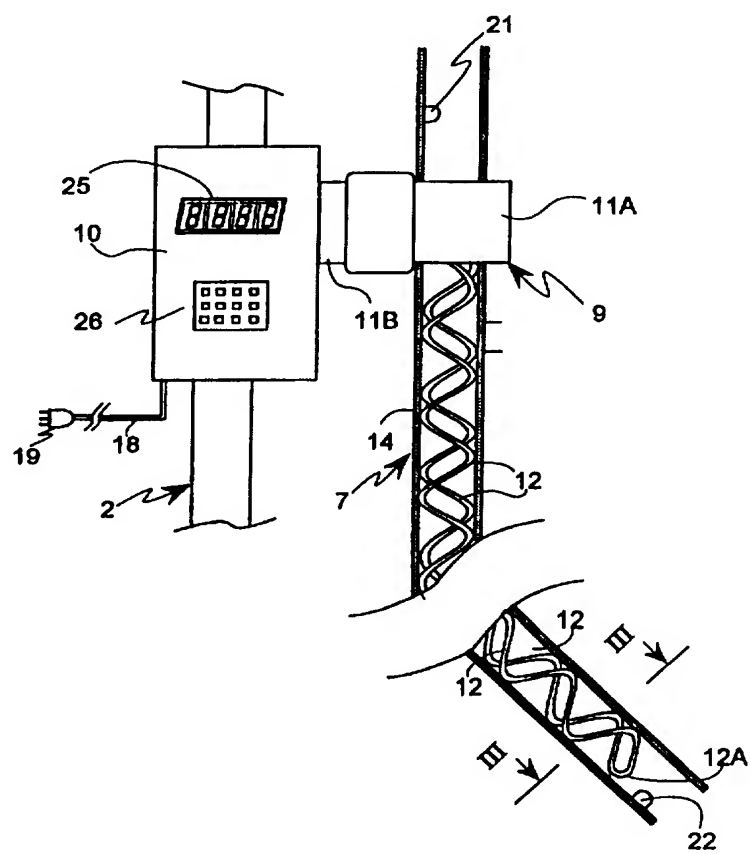
(54) Title: A DEVICE FOR ADMINISTERING WARMED LIQUIDS TO A PATIENT BY INTRAVENOUS INJECTION

(57) Abstract

A device for administering warmed liquids to a patient by intravenous injection, comprising a delivery flexible tube (7) adapted to be distributedly heated along at least a length thereof. An electrically dissipative element (12) is embedded in the wall (14) of the flexible tube (7) and is connected to power supply means (9) for applying to said dissipative element (12) a voltage that varies with time in response to the temperature of the liquid being injected. The flexible tube can further incorporate auxiliary electrical conductors (22A, 22B) connected to temperature sensors (21, 22) located along the tube. The dissipative element (12) can be fed either through a connector (11A, 11B) or inductively, through a transformer.



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"A DEVICE FOR ADMINISTERING WARMED LIQUIDS TO A PATIENT BY INTRAVENOUS INJECTION".

The present invention relates to a device for administering to a patient warmed liquids such as plasma, physiological and medical fluids, etc..

During surgery and intensive treatments medical liquids and/or blodd are administered to a patient by intravenous injection.

The blood is usually stored at about 4°C, while the physiological and medical fluids are stored at room temperature. During the infusion, the patient's blood is mixed with the infusion fluids and is cooled by these latter. Moreover the patient is often under anhestesia or unconscious so that the organism is unable to activate the usual defensive reactions with a consequent state of general hypothermia which in addition to being uncomfortable for the patient can severely interfere with other clinical aspects such as the reaction to drugs, hemorrhage, the cardiac rhythm, etc.

It has been suggested to heat a bag containing the fluid, or the first section of a delivery tube, in order to warm the fluid being infused to a temperature of about 37°C.

More particularly there have been known several devices and apparatuses capable of warming in a localized manner a fluid to be administered or injected into a patient.

For example EP-A-0 528 437 discloses an electric heater surrounding a section of the delivery line for pulsed heating the fluid at a place of the line, with the energizing duty cycle that is controlled by a monitoring unit incorporating a microprocessor and connected to temperature sensors.

EP-A-0 501 179 provides for a U-shaped container in which a medical fluid flows, connected to a source of electric energy for maintaining a constant temperature of the fluid.

EP-A-0 247 989 provides for a disposable tubular heat exchanger that is supplied with a warming fluid.

DD 213 352 discloses a blood warming equipment comprising a heater element having good heat conductivity and following the path of the blood flow in a blood-heating bag.

Additional known devices provide for local heating of blood or plasma in a bag by using microwaves (EP-A-0 307 895), or by means of electrically heated plates, with a portion of the delivery tube arranged to form labyrinthine passageways and in relation of thermal exchange with the plates (EP-A-0 292 076), or for the injection of sterilized fluids (FR-A-2 403 082).

However the known devices have drawbacks in that the blood, for example, cannot be heated above 42° without being subjected to permanent alterations, and therefore in most situations the relatively long distance from the heater to the patient is quite capable of reducing the temperature of the

infusion liquid to 20-22°C.

Another known device such as that disclosed in EP-A-0 256 653 provides for a distributed heating by using a heat exchanger having an inner tube for the blood flow and an outer tube providing a flow path for a heating fluid.

Similar problems are also faced in the intravenous injection of physiological fluids.

It has further been proposed a distributed warming system comprising a three-way delivery tube, i.e. having a central circular portion in which the fluid to be infused flows and two separate semi-annular portions for the flow (delivery and return, respectively) of a heating liquid such as water at about 40°.

The above distributed warming system is capable of preventing a thermal shock to the patient since the warming can be controlled up to the patient's arm, i.e. at the entrance into the body. However the systems providing a circulation of a liquid in thermal exchange relationship with the fluid to be infused require a pump for keeping the liquid circulating, usually water. Such a pump is noisy and cumbersome and moreover requires a periodic maintenance, including the replacement of the heating water even for sanitary reasons, and is nevertheless subjected to malfunctions.

Moreover the thermal exchange between the fluids

requires a tube diameter much larger in respect to that required for the mere infusion, which large tube becomes less flexible and thus uncomfortable to be used in the infusion. Finally, also due to its inertia, the system is not very satisfactory for an effective control of the real temperature of the liquid being injected.

The object of the present invention is to overcome the above mentioned limitations and shortcomings, and more particularly to provide a device for administering to a patient warmed liquids such as plasma, physiological and medical fluids and the like, wherein the temperature of the liquid is easily and precisely controlled, without appreciably increasing the diameter of the delivery tube, or increasing its stiffness. Moreover the construction of the device is simple and not expensive, and its working is reliable.

In accordance with the invention the above objects are achieved through a device as claimed in claim 1.

Additional advantageous features are recited in by dependent claims.

The invention will be now described with reference to the attached drawings illustrating a preferred but not limiting embodiment of the invention, in which:

Fig. 1 schematically illustrates the overall construction of the system for administering warmed liquids according to the invention;

Fig. 2 is a more detailed partial cross-section of an embodiment of the device according to the invention;

Fig. 3 is a cross-section view along lines III-III of Fig. 2;

Fig. 4 illustrates a connector for the electrical coupling to the heating means;

Fig. 5 illustrates another embodiment of the device according to the invention; and

Fig. 6 is a cross-section view of another embodiment of the delivery flexible tube.

With reference to Fig. 1, the illustrated administering system comprises a container 1, e.g. a bottle or a plastic bag containing the infusion fluid, for example a physiologic solution, plasma or other fluid to be injected, which is mounted on a holder 2, such as for example a vertical metal post resting on a base 3.

A first transparent flexible tube 5, such as a plastic hose, is connected between the lower outlet of the container 1 and a drip chamber 4, preferably through a choking device 8 restricting the flow by pinching the flexible tube. The drip chamber 4 allows a visual checking of the flow rate and its outlet is connected to delivery flexible tube or a hose 7, usually of plastic material, extending up to the patient's bed and connected to a needle 6 inserted into a vein of the patient. The plastic delivery flexible tube 7 is made for

example of PVC and/or polyurethane, and has a length of a couple of meters. A relatively rigid portion of the tube (not shown) can be employed for joining together flexible tubes 5 and 7.

In the device according to the invention, downwards the drip chamber 4 there are located power supply means 9, controlled by a monitoring or central unit 10 that is secured to the supporting rod 2, both of which are disclosed with more details later on with reference to Figures 2 and 5.

With reference to Figures 2 and 3, according to the invention at least a portion of the delivery flexible tube 7, but preferably the whole length of the flexible tube extending from the drip chamber to the patient, is provided with electrical heating means in form of one or more distributed dissipative elements (i.e. capable of turning electrical power into heat). More particularly, at least one electrical conductive means or conductor 12 is embedded or incorporated within the inner surface of the plastic wall 14 of the flexible tube 7. Preferably the above conductor is completely merged within the wall 14 of the delivery flexible tube, however the conductor could be only partially embedded within the wall 14, or in case merely made to adhere to the inner surface of the delivery flexible tube (see Fig. 6), and suitably covered by a protective coating of plastic material.

By using very low supply voltages, such as for example

voltages in the order of 6 Volts, the electrical (linear) resistivity can be in the order of a few Ω/cm, and is a function of the cross-section area of the conductor(s) 12. Indicatively the overall required electric power is not greater than 200 Watts, aven in case the fluid to be heated is just thawed blood.

Preferably the conductor 12 is a metal one, having a flat cross-section and substantially laid along an helical path. In the preferred embodiment illustrated with reference to Figures 2 and 5, the conductor 12 forms two helical paths each having one end connected together (i.e. shortcircuited) inside the flexible tube at 12A, with the other ends being electrically connected to the power supply means 9.

Of course there are possible other embodiments of the dissipative elements, as long as they are biologically compatible and adapted to realize distributed dissipative means, such as for example a metal foil, a deposition of metallic (or at least conductive) material, etc. Preferably the delivery flexible tube 7 is formed by extrusion of plastic material.

A further embodiment of the dissipative means, not shown in the drawings, provides for two low-resistance electrical conductors that are substantially parallel to each other, and concentrated resistive elements, e.g. of resistive inks or other material having an appreciable resistivity are connected

between said two conductors at regular intervals, with all such conductors and resistive elements being completely embedded within the thickness of the wall 14 of the flexible tube 7.

The power supply means 9 is capable of applying to the distributed heater formed by the conductor(s) 12 a voltage that varies with time, preferably a sinusoidal voltage having an amplitude not higher than 20-30 V.

In accordance with a preferred embodiment shown in Figures 2-4, the power supply means 9 includes a male connector member 11A mechanically fastened to the tube 7 and provided with at least two terminals 31, 32 that are electrically connected to the ends of conductor(s) 12. A corresponding female connector member 11B is fastened to the control unit 10 or in case to the rod 2, and is connected to the male connector 11A, as shown in Figure 2.

Of course the locations of the male and female connector members can be reversed, if desired.

Connector 11A can include additional terminals, shown at 33, 34, and 35, 36 for being connected to additional sensors that might be located along the delivery flexible tube 7, as will be illustrated later on.

The delivery flexible tube 7 according to the invention can further incorporate auxiliary electrical conductors (22A, 22B in Figure 3) for temperature sensors 21 and 22, preferably

thermocouples located upwards and downwards the heater. The two sensors 21 and 22 are connected to the control unit 10 that in turn, using known techniques and a microprocessor or the like, adjusts the supplied power for keeping the fluid output temperature within a prescribed range.

The control unit 10 is connected through a cable 18 and a plug 19 to the mains and preferably further includes a keybord 26 and a display 25.

The voltage control can change the amplitude of the supplying voltage, or even supply a portion of a sinusoidal waveform by using tyristors or similar controlled switching devices, or generate a train of voltage pulses having a duration - e.g. a duty cycle - that is variable, and so on.

Preferably the flexible tube-connector assembly is realized as an integral and sterilized component to be disposed after use.

Another embodiment of the invention is illustrated in Figures 5 and 6 where the same references have been used for equal or similar parts, these parts being therefore not further discussed.

According to this embodiment, the power tranfer takes place inductively and the means 9 includes a transformer with a primary winding connected to the unit 10 and the secondary winding electrically connected to the distributed dissipative element 12.

In the embodiment shown in Figure 5, such windings are in form of coaxial coils wound on substantially cylindrical supports that are not shown, with the secondary winding 16 surrounding a portion of the delivery flexible tube 7 and secured thereto, in case in a not permanent manner. Advantageously the coil is slightly forced over the tube in correspondence of external contacts (not shown) leading to the conductor 12. The coil 15 of the primary winding has an inner diameter substantially corresponding to the outer diameter of the secondary coil 15, still allowing an axial movevent in respect of the former. The support of this coil 15 is provided with a lower supporting portion having a reduced diameter to support the coil 15 of the primary winding together with the tube 7 secured thereto.

As an alternative, the tube-coil assembly can be formed as a single inseparable component to be disposed of after a predetermined number of uses.

The device of the invention, through relatively simple and easy calibration and data storage operations, can be used for determining the flow rate of the injected fluid from the power supplied to the fluid under steady conditions.

The device of the invention does not increase the filling volume, i.e. that portion of the fluid which remains in the tube at the end of the infusion), ad eliminates any risk of thermal shock since it allows for a progressive and

controlled warm up of the fluid to a desired temperature at the point the fluid enters the patient's circulatory system.

Although "reinforced" by the presence of conductor(s) 12, the delivery flexible tube 7 substantially maintains its flexibility and the original diameter, with an additive cost which is in practice negligible.

The device of the invention eliminates all moving parts and allows an extremely precise and quick control of the temperature of the fluid being injected.

Although the invention has been disclosed with reference to preferred embodiments, the invention is generally capable of applications and modifications that are to be included in the protective scope of the invention as will become apparent to the skilled of the art.

CLAIMS

1. A device for administering a warmed liquid to a patient, comprising a delivery flexible tube (7) adapted to be distributedly heated along at least a portion of said delivery flexible tube (7), and means (10) for controlling said heating, characterized in that the wall (14) of said flexible tube (7) incorporates, for at least a portion of its length, at least one electrically dissipative element (12) connected to power supply means (9) that applies to said dissipative element (12) a voltage that varies with time in response to the temperature value of the liquid being injected.

2. A device as claimed in claim 1, characterized in that said power supply means (9) comprises a connecting member (11A) mechanically secured to said delivery flexible tube (7) and provided with at least two terminals (31, 32) that are electrically connected with said electrically dissipative element (12), and a connecting member (11B) mating with the former and connected to said control means (10).

3. A device as claimed in claim 1, characterized in that said power supply means (9) includes an electrical transformer having a primary winding (15) and a secondary winding (16) coupled together for inductively transmitting electrical power, said secondary winding (16) being electrically connected to said distributed dissipative element (12).

4. A device as claimed in claim 3, characterized in that

said two windings are in form of coaxial coils (15, 16).

5. A device as claimed in the preceding claims, characterized in that said dissipative element (12) includes at least one conductor means (12) embedded or incorporated within the wall (14) of the delivery flexible tube (7).

6. A device as claimed in claim 5, characterized in that said conductor means (12) defines two helical paths having the inner ends shortcircuited inside the flexible tube (12A) and the other two ends electrically connected to the power supply means (9).

7. A device as claimed in claim 5, characterized in that said wall (14) of the delivery flexible tube (7) further incorporates auxiliary electrical conductors (22A, 22B) connected to temperature sensors (21, 22) for measuring the temperature of the liquid being injected.

8. A device as claimed in claim 7 being dependent from claim 2, characterized in that said connector (11A, 11B) comprises terminals (31, 32) for said auxiliary conductors.

9 A device as claimed in claims 5 or 6, characterized in that said at least one conductor means (12) is a flat conductor.

10. A device as claimed in claim 9, characterized in that said flat conductor (12) is formed through deposition of an electrically conductive material.

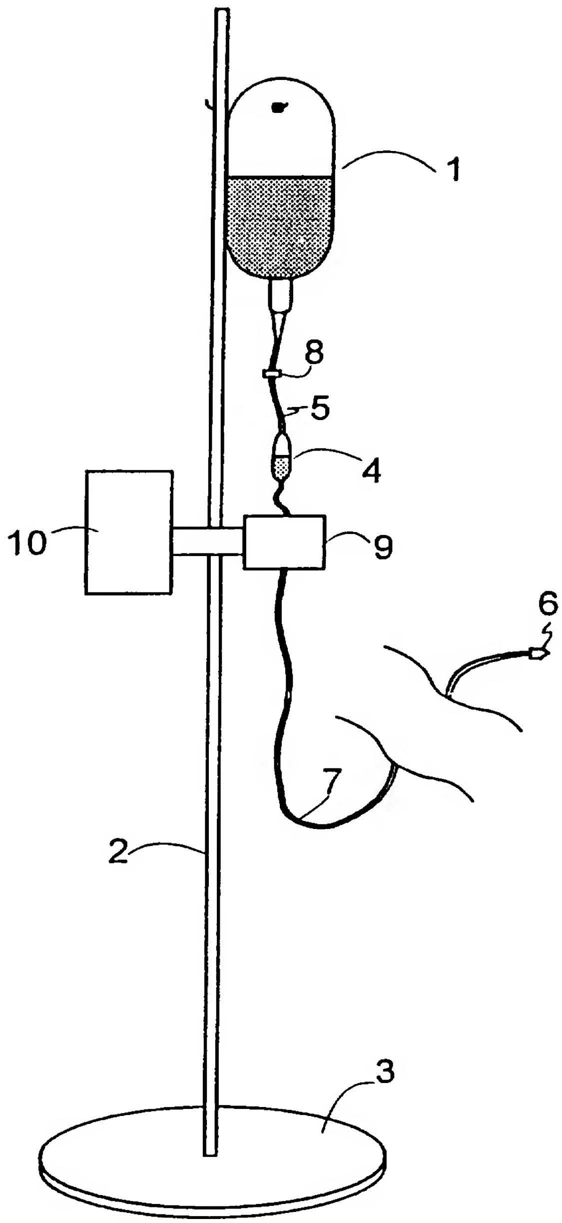
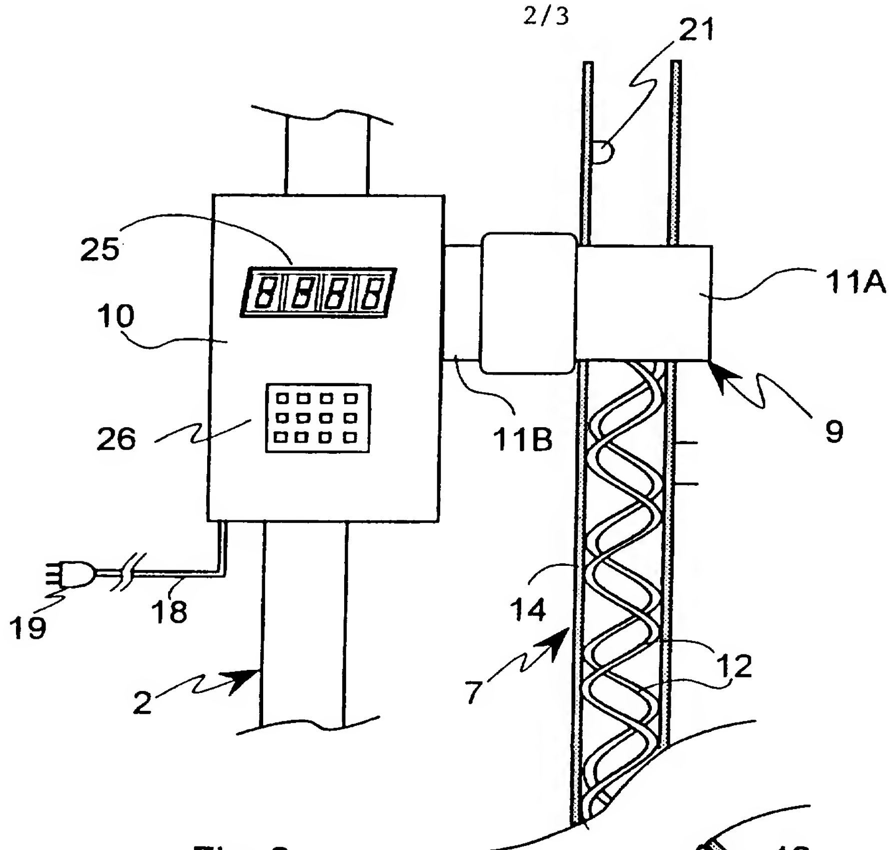


Fig. 1



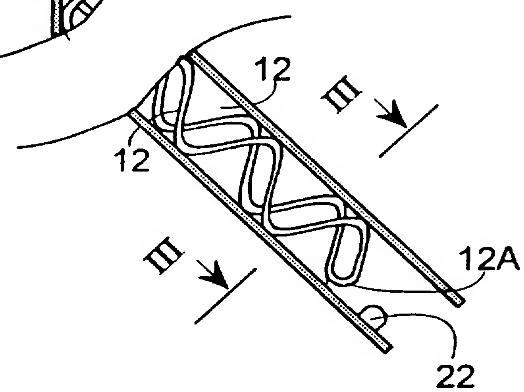


Fig. 2

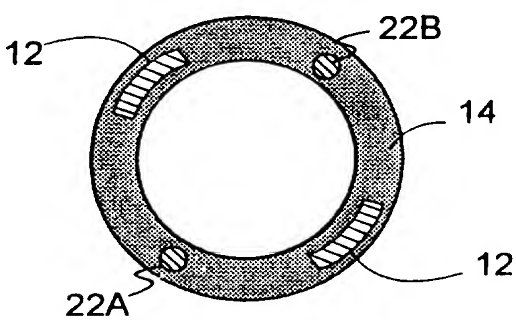


Fig. 3

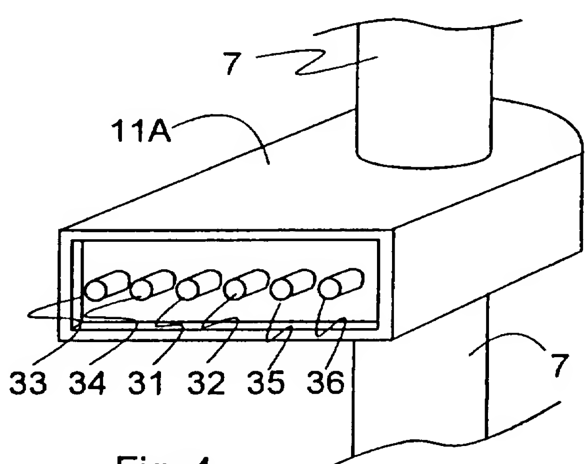


Fig. 4

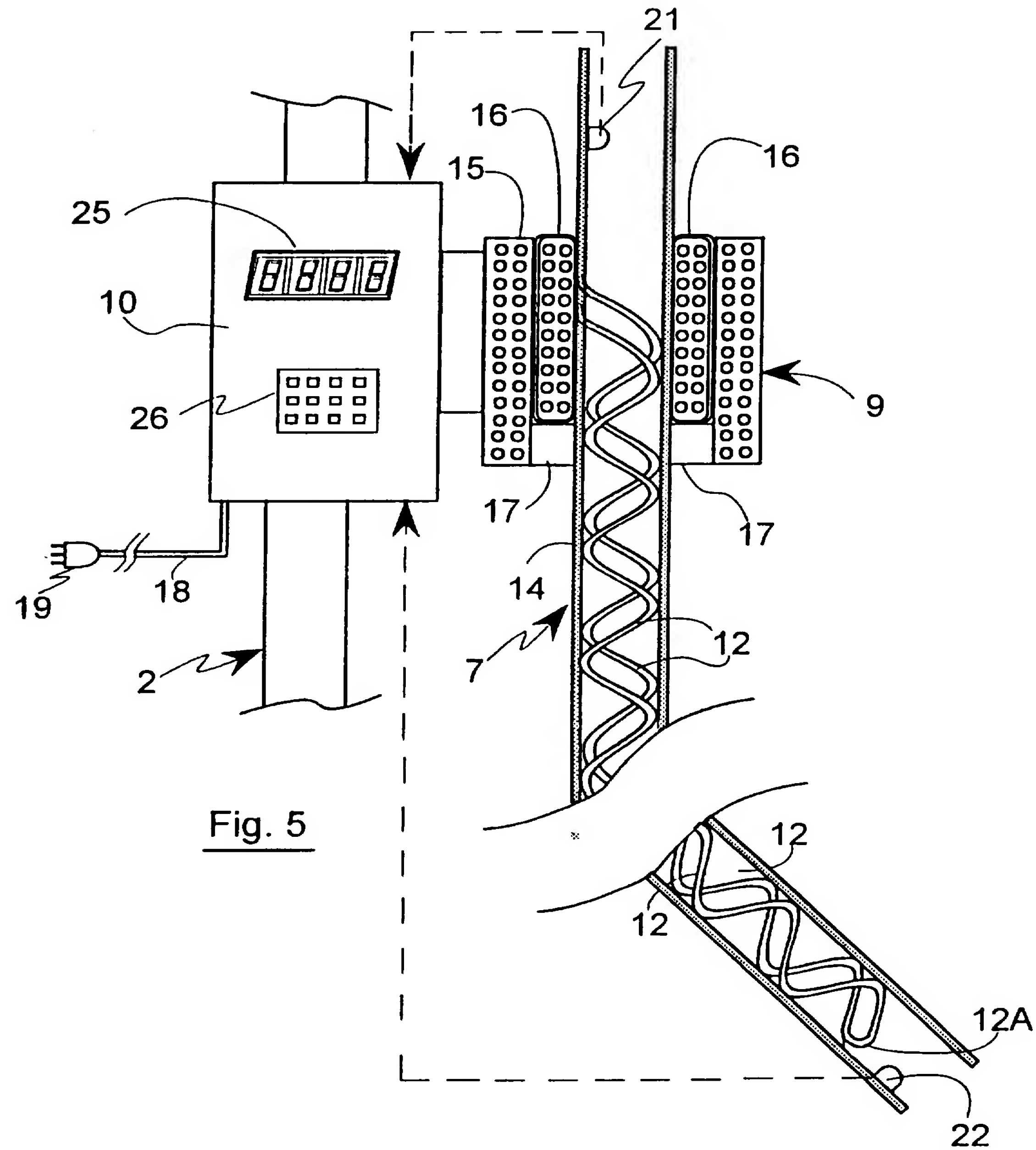


Fig. 5

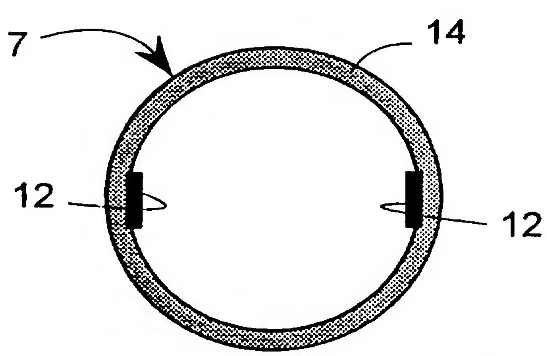


Fig. 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 95/03895

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE,A,24 54 349 (RHONE-POULENCE S.A.) 3 July 1975 see page 1, line 16 - page 4, line 10 see page 9, line 14 - line 23 see figures 1-4	1,2,5-9
Y		3,4
Y	US,A,5 319 170 (CASSIDY) 7 June 1994 see column 3, line 9 - line 65 see figures 1-3	3,4
X	CH,A,198 839 (SCHULER) 1 October 1938 see page 1, column 1, line 21 - column 2, line 6 see page 2, column 1, line 14 - column 2, line 10 see figures 1,3	1,5

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
22 January 1996	26.01.96

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
DE-A-2454349	03-07-75	FR-A-	2251769	13-06-75
		FR-A-	2287637	07-05-76
		BE-A-	822237	14-05-75
		CA-A-	1022221	06-12-77
		CH-A-	591039	31-08-77
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		JP-B-	54030232	28-09-79
		NL-A-	7414546	20-05-75
		SE-A-	7414339	16-05-75
		US-A-	4038519	26-07-77
US-A-5319170	07-06-94	NONE		
CH-A-198839		NONE		